

## Report Against Acupuncture For Anesthesia Stirs Debate

Medical Tribune World Service

FLORENCE, ITALY—A straightforward denial that acupuncture provides effective anesthesia during surgery in the Western sense of the concept was delivered at the First World Congress on Pain by Dr. Arthur Taub of the department of anesthesiology, Yale University Medical School. He termed acupuncture anesthesia "natural surgery" in an analogy with "natural childbirth," in which reduction of pain is produced in selected individuals by indoctrination combined with social motivation.

Instances where no pain is reported are "anecdotal evidence" of the kind which can also "be gathered about pa-

tients who have undergone major surgery for various reasons without any local or narcotic analgesic or needle anesthesia whatever and have denied pain," he said, and can reasonably be attributed to the placebo effect.

Dr. Taub, who specializes in pain research, based his conclusions on observations during a visit to China in May, 1974 (as part of a group of ten American experts) designed specifically to study acupuncture anesthesia.

Acupuncture is not widely used as anesthesia in surgery in China, Dr. Taub pointed out. On the contrary, local, regional or general anesthesia is employed in about 90 per cent of cases,



At Peking Medical College teaching hospital, operation is performed under acupuncture anesthesia on patient with cancer of the cardia and lower esophagus. Three needles were inserted at points on the left ear and forearm.

general anesthesia being least favored since sleep and coma are associated in popular thought with the departure of the soul from the body. Patients like to be awake during surgery and Chinese physicians do not have extensive experience with general anesthesia.

Where acupuncture is used, he continued, it is on an experimental basis in major surgical centers where trained anesthesiologic backup is available. It is never used in emergency procedures or poor risk patients and very rarely in juveniles. It is essentially voluntary and patients must be in good health and emotionally stable, "that is, capable of lying motionless, awake, on an operating table for several hours."

### Patients Premeditated

Patients selected for acupuncture anesthesia usually receive premedication with barbiturates (up to 500 mg of phenobarbital), narcotic agents (50-100 mg of meperidine I.V.) which may be repeated every two hours during surgery, and sedating agents, Dr. Taub said. Local anesthesia is an integral part of the technique, and may be used for incision through and manipulation of fascia, pleura and peritoneum, viscera and sometimes skin.

Dr. Taub further took issue with official Chinese criteria of success. "Acupuncture 'anesthesia' neither produces 'anesthesia' nor 'analgesia' in the conventional sense," he said. According to the classification system used in Shanghai, he explained, grade I, or an "excellent" effect, allows for "slight pain" and the use of intravenous meperidine and local anesthesia.

Grade II, or good, permits "occasional light groans," changes in blood pressure and pulse and respiration rates, meperidine and local anesthetics. Grade III, or "moderate" success, permits "obvious" pain and "obvious" changes, and increased meperidine as well as "moderate" local anesthesia.

All three grades are considered effective in China, whereas only a portion of grade I would pass the test in the U.S., Dr. Taub pointed out.

Using as an example the statistics published by the Shanghai Acupuncture Anesthesia Coordinating Group in 1973 for 656 cases of pulmonary resection in which acupuncture anesthesia was used, he noted that 161 were grade I, 171 grade II and 346 grade III, while 23 fell into grade IV. The "effective" rate was reported as

Continued on page 18

## If there's good reason to prescribe for psychic tension...



When, for example, reassurance and counseling on repeated visits are not enough

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### Editorial

## Congratulations

MEDICAL TRIBUNE EXTENDS CONGRATULATIONS to the key officials of the FDA for a landmark public health decision—the labeling of alcoholic beverages under FDA control. The action of Commissioner Alexander M. Schmidt, the physician who heads FDA, Dr. Richard Crout, its Director of the Bureau of Drugs, and Mr. Sam Fine, Associate Commissioner for Compliance of the FDA, introduces logic as well as consistency, proper public health perspectives and priorities into food and drug regulation. It also demonstrates that there are unselfish officials in our health bureaucracy who can

place the interest of the public and the national health ahead of personal ambition and job security, ahead of political or bureaucratic expediency.

...Lest We Celebrate Prematurely...

BUT WE CELEBRATE PREMATURELY, let us recognize that "the chips are down." In view of the history or tokenism in health

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# Medical Tribune

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—and Medical News—

Vol. 16, No. 44

world news of medicine and its practice—fast, accurate, complete

Wednesday, December 17, 1975

### Current Opinion

## Our Readers Write about the President's Cold, Dr. Lasagna's Letter, and Dr. Sackler's View

MEDICAL TRIBUNE has been deluged with letters from physicians in response to Dr. Lasagna's letter and Dr. Sackler's column (Nov. 19) pointing out that Dr. William Lukash treated President Ford's cold with an antibiotic while FDA and HEW physicians indicted practicing physicians for doing just what Dr. Lukash did. Dr. Lasagna's letter pointed out most patients do not visit physicians for common colds but treat themselves—and come to the physician only when secondary bacterial complications have set in. Dr. Lasagna's letter is reprinted again on page 19. Responding physicians offered the following opinions:

• Thank you for the most interesting yet controversial aspect of the President's recent cold.

WILLIAM M. LUKASH, M.D.  
Rear Admiral, MC, USN  
Physician to the President  
The White House  
Washington, D.C.

• Dr. Lasagna is absolutely right! Personally, I have never prescribed an antibiotic for a "cold."

Complications of a cold such as bronchitis with purulent sputum, or patients with a history of rheumatic fever, nephritis, or previous streptococci if there is an accompanying acute pharyngitis, definitely yes.

EDWARD W. NICKLAS, M.D.  
Washington, D.C.

## Doctors Cited for Failure To Biopsy Early Breast Ca

Medical Tribune Report

SAN FRANCISCO—Although more cancers are being detected at an early stage by combined breast-screening modalities, many doctors reportedly fail to biopsy patients with "clinically occult" radiographic evidence of early disease.

Consequently, Dr. Gordon F. Schwartz, Associate Professor of Surgery at Jefferson Medical School in Philadelphia and Director of the Breast Diagnostic Center (BDC) has recommended devoting "more efforts at educational programs among the medical profession, demonstrating the value of these ancillary techniques of diagnosis."

Using thermography, mammography, and clinical examination, the BDC has since 1973 found 106 new tumors in 16,345 examinations of asymptomatic, self-referred

Continued on page 5

### Senator Kennedy Charges

## FDA 'Doesn't Work,' Should Be Split into Separate Agencies

By NATHAN HORWITZ  
Medical Tribune Staff

NEW ORLEANS—Plans for a sweeping legislative overhaul of the Food and Drug Administration that would divide it into two agencies—one exclusively responsible for supervision of drugs, the other over foods and cosmetics—were announced here by Sen. Edward M. Kennedy (D., Mass.).

The Senator, who will introduce his proposed legislation in this session of Congress, said the FDA as now constituted simply "doesn't work." In one of the harshest criticisms of the agency yet made by a national figure, Mr. Kennedy charged the FDA is "understaffed, underfunded, overextended" and lacking in adequate scientific knowledge to do its job. It delays approval of useful drugs and allows its scientific advisory committees to be used as "rubber stamps" for staff decisions, the Senator charged.

Continued on page 13



FDA Chief Dr. Alexander M. Schmidt explains plans to speed drug trials and follow-up. Changes would affect major test procedures.

## Atherosclerotic Plaque Reduced Dramatically by Cholestyramine

Medical Tribune Report

ANAHEIM, CALIF.—Cholestyramine has produced "dramatic" regressions of severe atherosclerotic lesions in primates with experimentally induced atherosclerosis, a University of Chicago team has reported.

The drug was most effective when given in combination with a low-fat, low-cholesterol diet, but even when combined with an atherogenic diet it produced "some evidence of regression" of the atherosclerotic plaques, Dr. Robert W. Wissler, Donald N. Pritsker Professor of Pathology, told the American Heart Association here.

Continued on page 20

making rounds at press time

NEW YEAR'S DAY may find Suburban Hosp. in Bethesda, Md., without 24 obstetrician-gynecologists. They've voted to quit and take pts. else-

## 'B' Fragment Receptors Identified in Kidney

By MICHAEL HERRING  
Medical Tribune Staff

BETHESDA, Md.—Specific receptors for the "b" fragment of the third component of complement (C3b) have been identified in the kidney's glomerulus by a team of National Institute of Allergy and Infectious Diseases (NIAID) scientists, the institute recently reported.

The finding may lead to the development of immunotherapy against renal diseases such as glomerulonephritis. Dr. Michael Gelfand told MEDICAL TRIBUNE. Dr. Gelfand is Co-Director of the Hemodialysis Unit at Georgetown University Medical Center in Washington, D.C., and a guest worker at NIAID.

"If the receptor indeed mediates immune-complex renal disease, and if there are a finite number of receptors, then one can envision producing a molecule that is structurally similar to the pathogenic C3b molecule, one that would occupy the glomerular receptor site, but not activate subsequent complement components," Dr. Gelfand explained.

### Complement Cascade

C3b, he added, is number three in a series of "circulating protein" interactions leading to a complement component with cell- and tissue-destroying properties. "The complement cascade is comparable to the clotting mechanism," Dr. Gelfand said. "Or think of a house of cards. Once the first component is activated, it sets off the next, which in turn sets off the third and so on."

"Antigen-antibody complexes can precipitate the complement cascade. This is the case in immune-complex or antigen-antibody-complex renal diseases, such as poststreptococcal glomerulonephritis or systemic lupus erythematosus. When the protein reaches the C3b stage, it seems to be bound by the renal receptors."

The "cascade" reaction continues from there, Dr. Gelfand said, until a lytic complement protein is produced, causing loss of tissue and blood supply.

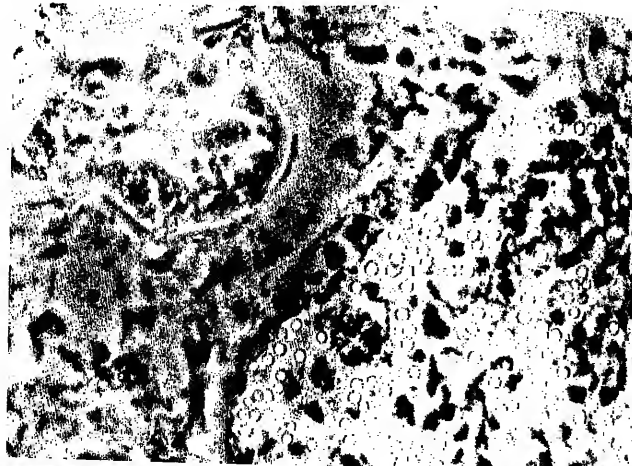
## Radiotherapy Seen Not Depressing Immunity

Medical Tribune Staff

SAN FRANCISCO—Though radiotherapy may cause some short term depression of cell mediated immunity, it apparently has no late or long-term effects on either cell mediated or humoral immunity. That was the conclusion reached by Dr. Martin Halli and associates at Albert Einstein College of Medicine after a prospective, three-year study of 52 patients.

Reporting here at the American Society of Therapeutic Radiologists, Dr. Halli said the study showed that large field irradiation had no late effect on either cell mediated immunity as determined both by skin reactivity to DNCB (2,4-dinitrochlorobenzene) and by the absolute lymphocyte count, or on the humoral circulating immunoglobulins.

There has been some controversy about the short-term effect of local ir-



In normal kidney tissue above, ringed sheep red blood cells, coated with C3 (complement) and antibody, adhere only to clusters of blood vessels in portion of glomerulus shown at

right. Glomerular receptors apparently bind the "b" fragment of C3, leading to renal diseases such as glomerulonephritis. Future immunotherapy may entail blocking receptors.

of the third component—the port that actually binds with the receptor," Dr. Gelfand told MEDICAL TRIBUNE.

"We've also examined a one-day-old child who died of nonrenal causes and had apparently normal kidneys, and found similar evidence for the presence of renal receptors. So it seems that it's natural to have them from birth," he said.

While it appears conclusive that receptors for C3b do exist, Dr. Gelfand stressed that extrapolations of the findings are preliminary, and that further research is required to pinpoint the exact site of receptors and develop appropriate immunotherapy.

Dr. Frank is Chief, NIAID Laboratory of Clinical Investigation, and Dr. Green is Senior Investigator, NIAID Laboratory of Immunology.

## Child's Exploratory Behavior Impaired by Malnutrition

Medical Tribune Staff

ITUACA, N. Y.—Research at Cornell University suggests that prenatal and neonatal malnutrition do not impair intellectual development by actual physical damage to brain cells, but rather by preventing the child from learning certain kinds of information. David A. Levitsky, Ph.D., of the university's division of nutritional sciences, told the Cornell Conference on Malnutrition and Behavior.

Malnutrition seems to delay eye-muscle coordination in the young and to increase maternal protectiveness, both of which tend to depress the child's environmental curiosity and to inhibit exploratory behavior, Dr. Levitsky said.

normal population where 90 to 95% will be DNCB reactive," Dr. Halli noted.

He found also that white blood cell count and absolute lymphocyte count were within the normal range, and that the serum immunoglobulins (IgA, IgM, and IgG) evaluated in 22 patients were also within the normal range.

He did find, he added, that cell-mediated immunity was affected by age and that the response to DNCB was affected by the strength of the challenge dose. Thus, the overall reactivity for a 100 microgram challenge dose was 87%, for the 50 microgram dose it was 65%, and for the 25 microgram dose it was 44%. Similarly, there was a decrease in the number of positive DNCB reactors as the age increased, despite the size of the challenge dose, Dr. Halli said.

### Croton Oil Reaction

At the time of the DNCB challenge, the patients were also tested with 10% the inflammatory response. A white lymphocyte count calculated absolute serum immunoglobulins were obtained by immunodiffusion, Dr. Halli said.

He found that 87% of the patients were DNCB reactive and 85% were in those tested prior to radiotherapy in a previous study and approaches that of a

## Cancer Gene 'Mapped' on Tumor Virus

By FRANCES GOODNIGHT  
Medical Tribune Staff

COPENHAGEN, DENMARK—An essential step in understanding how viruses induce cancer has been achieved by investigators at the University of California in Berkeley, who reported here that they have "mapped" on a tumor virus molecule the precise location of the gene that causes cells to become malignant.

The research team also determined the location of the gene that controls formation of the protein envelope surrounding the virus particle.

Their work, described at the Seventh International Symposium on Comparative Leukemia Research, is believed to be the first such gene mapping in a virus that causes naturally occurring forms of animal cancer.

### Avian Tumor Viruses Used

The Rous sarcoma virus and other avian tumor viruses were used in the experiments, which were conducted by Peter H. Duesberg, Ph.D., Lu-Hui Wang, and Karen Beemon, Ph.D., with colleagues at the university's virus laboratory.

What led to the mapping was their discovery that some avian sarcoma viruses grown in culture changed by mutation into a "deletion mutant"—one that could still produce a leukemic effect in test animals but was incapable of transforming normal cells to a cancerous state.

By comparing the original tumor virus with the mutant, the investigators determined that the latter contained

about 15% less genetic material. They then broke RNA molecules from both viruses into fragments (oligonucleotides) with an enzyme and subjected them to a "fingerprinting" process designed to separate groups of chemical subunits by their varied properties and electric charges.

The results confirmed the biologic tests, demonstrating that sarcoma-specific fragments in the avian tumor virus were not present in the mutant version, and that the missing fragments constituted about 15% of the total material.

The Berkeley group had established that one end of the sarcoma virus RNA molecule is marked by some 200 adenine units strung together. Since this Poly (A) unit can be tagged by linkage to other units, the investigators again fragmented such tagged RNA molecules and found that the cell-transforming activity was close to the Poly (A) end of the molecule, in a cluster of oligonucleotides that represent the "oncogenesis" gene.

Mapping of the envelope was achieved by similar sophisticated tests, using a mutant sarcoma virus that lacked an outer envelope but retained its ability to transform cells.

Still to be mapped, the investigators noted, are the genes governing the polymerase enzyme responsible for nucleic acid replication and the gene that controls formation of the inner protein coating of the virus.

They now plan to analyze the more complex mammalian cancer viruses, with the goal of spelling out the genetic code of viral segments and finding out how the gene message is carried to the point where normal cell processes are disrupted and malignant changes occur.

### Viruses in Leukemia

An overview of symposium reports dealing with new concepts of the role of viruses in human leukemia was subsequently presented in New Orleans at the Leukemia Society of America by David S. Yohn, Ph.D., director of the Ohio State University Cancer Research Center, Columbus.

Dr. Yohn cited morphologic, immunologic, and biochemical evidence for human RNA leukemia viruses and concluded: "The evidence is overwhelming that RNA tumor viruses are associated with human leukemia, probably etiologically."

But it is equally evident, the investigator declared, that no proven human leukemia virus has as yet been isolated.

He summed up two predictions: In the next five years, trials will be carried out in mice and cats to determine whether pure vaccines prepared from glycoprotein (gp 69/70) antigens of known RNA tumor viruses, such as feline leukemia virus, murine leukemia virus, and avian sarcoma virus, will protect these animals from naturally occurring virus-induced leukemia.

If such animal trials are successful, by the end of the century similar trials will be underway in patients. The studies will be carried out with purified gp 69/70 antigens known to cross-react with human leukemia cells.

And it is "just possible that a preventive vaccine against human leukemia will be established by the year 2000," Dr. Yohn said.

### Leukemia Therapy

Immunotherapy combined with chemotherapy in clinical trials in patients with acute myelocytic leukemia produced longer remission durations than did chemotherapy alone, according to J. George Bekesi, Ph.D., and colleagues of Mount Sinai School of Medicine, New York.

Patients in whom remission had been achieved by cytosine arabinoside and daunorubicin were allocated to two groups for the trials. Both received cyclical maintenance chemotherapy every four weeks. Patients randomized to receive immunotherapy were also given neuraminidase-treated allogeneic myeloblasts, injected intradermally at monthly intervals in approximately 40 sites in different drainage areas.

Of 10 patients who had received previous antileukemic chemotherapy, the six immunized patients had more than twice the remission duration of the four controls, the investigators said.

Among 18 patients previously untreated, the median remission duration for nine patients on chemotherapy alone was 22 weeks. In contrast, six of the nine patients receiving the combined therapies remain in remission from 68 to 115 weeks.

### Drug Selection

A biochemical test that may help physicians determine which of two recommended drugs to select for a given patient with acute myelogenous leukemia (AML) was described by Dr. Bruce A. Chabner, of the National Cancer Institute.

The test may also indicate whether or not an AML patient is apt to respond to either of the two agents—cytosine arabinoside (ara-C)—and prospective trials of the test are now underway, Dr. Chabner said.

Both drugs have chemical structures similar to naturally occurring nucleosides and thus compete with such nucleosides for enzymes essential to the synthesis of DNA.

In studies of 44 previously untreated AML patients, blast cells were tested for activity of deoxycytidine kinase, the enzyme that activates ara-C; uridine-cytidine kinase, the enzyme thought to activate 5-aza-C; and cytidine deaminase, the enzyme that converts both drugs to an inactive form.

Dr. Chabner and coworkers found that the patients had markedly different potentials for activating or deactivating the drugs. Enzyme levels varied independently, with no apparent relationship to the subclass of the leukemias or to sex.

Next week Dr. Sackler will address the "range problem" of "The Three Horsemen of Death"—Alcohol, Tobacco and Firearms—being under the jurisdiction of the U.S. Treasury Department.

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CLINICAL NEWS NOTE: "Monkeys treated" with cholestyramine show a substantial decrease in lumen narrowing as compared to the reference group autopsied at 12 months... With this kind of evaluation, we can say with confidence that we have stopped the progression of coronary and aortic disease... (Dr. Robert W. Wissler, Professor of Pathology, University of Chicago, Pritzker School of Medicine. See page 1.)

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## IN CONSULTATION

## What's New and Important in the Management of Asymptomatic Carotid Bruits



### The Consultant

Dr. Jesse E. Thompson

Department of General Surgery  
Baylor University Medical Center  
Dallas, Tex.

**D**URING THE PAST TWO DECADES, it has been clearly established that in many patients with cerebrovascular insufficiency the responsible atherosclerotic occlusions are in the extracranial vasculature. In fact, Hass et al state that 74 % of such patients have at least one significant lesion at a surgically accessible site. It is, therefore, technically feasible to increase cerebral blood flow by surgical means. Carotid endarterectomy is highly effective in the treatment of patients with transient cerebral ischemia, since symptoms are relieved in most instances and the incidence of subsequent strokes is markedly reduced.

The most controversial area in this field concerns the advisability of performing arteriography and surgery on patients with asymptomatic carotid bruits. Asymptomatic subclavian bruits, even with a demonstrated subclavian steal syndrome, do not require operative intervention. The mid-carotid bruit, however, reflecting the presence of atherosclerosis at the common carotid bifurcation is another matter. The majority of such bruits arise from internal carotid plaques, the rest coming from external carotid plaques or other uncommon lesions. The indications for endarterectomy in patients with asymptomatic carotid bruits, however, have not yet been clearly defined.

A safe, simple, and reliable noninvasive screening technique has been needed. Karchner and his associates have reported the use of the oculo-plethysmogram as a noninvasive screening method to determine the significance of carotid bruits. The report of these authors to date has been very encouraging with the OPG giving 91 % accurate results when correlated with the arteriogram, a 6 % incidence of false-negatives, and a 3 % incidence of false-positives.

**Do you recommend auscultation of the neck as a routine measure?**

Auscultation of the neck for the presence of carotid bruits is an important examination in patients with cerebrovascular insufficiency syndromes. In fact, this should be done to every routine physical examination, especially in patients over the age of 40 and in those with evidence of atherosclerosis elsewhere in the body. The standard 3 cm bell atheroscope remains the most satisfactory one for cervical auscultation.

The differential diagnosis of cervical murmurs includes physiologic murmurs of no significance; venous hum; arteriovenous fistula; angiomatous mal-

formations; intracranial neoplasm; Paget's disease of the skull; fever; anemia; thyrotoxicosis; atherosclerosis of the aorta; subclavian, vertebral and carotid arteries; loops, kinks and fibromuscular dysplasia of the carotid artery; and transmitted cardiac murmurs.

In children and young adults cervical murmurs are of little significance. They are usually heard at the base of the neck and their incidence decreases rapidly with increasing age. Over the age of 40, however, cervical murmurs are much more significant, the carotid bruits being those most commonly encountered.

**What distinguishes the carotid bruit?**

The most important cervical bruit is the mid-carotid, heard over the carotid bifurcation near the angle of the jaw. It is usually highly localized and disappears quickly as one listens inferiorly. Carotid bruits vary in intensity from soft to very harsh and may be graded from 0 to 4+ on a quantitative basis. They appear when stenosis is 50 % or greater and may actually disappear at 85 to 90 % stenosis.

A carotid bruit when present is a significant finding in patients with cerebrovascular insufficiency. The controversy arises as to the significance of the bruit in the absence of cerebral symptoms.

**How do you consider the asymptomatic bruit?**

It does not appear unreasonable to consider the asymptomatic carotid bruit as part of the total picture of cerebrovascular insufficiency rather than an isolated finding on physical examination. The natural history of ischemic thrombotic stroke due to extra-cranial lesions must begin somewhere. It may begin as a plaque at the common carotid bifurcation and its first physical manifestation be an asymptomatic bruit. With time the asymptomatic lesion becomes symptomatic from ulceration and embolization or from impairment of cerebral blood flow. Hopefully the first symptom is a TIA, when therapy can be initiated. At times, how-

ever, the first symptom is hemiplegia, especially if a stenotic carotid undergoes acute total occlusion.

Javid et al have studied the natural history of carotid atheromas on serial arteriograms over a period of one to nine years. They noted no change in size of the atheromas in 38 % of the lesions studied but found a significant increase in 62 % of the atheromas. The increase was greater than 25 % per year in 34 % of lesions, was less than 25 % per year in 20 %, while recurrent stenosis or thrombosis occurred in 7.4 %.

During the past 18 years my colleagues, Drs. R. Don Potmon and Alfred V. Persson, and I have performed more than 1100 carotid endarterectomies for the various syndromes of cerebrovascular insufficiency. During this time we have had the occasion to see a number of patients with asymptomatic carotid bruits. In one series of 119 elective operations upon 84 patients with asymptomatic bruits there has been no operative mortality. General anesthesia was used together with a temporary infusing shunt routinely for cerebral protection. There have been two neurologic deficits associated with operation, both permanent and both mild, an incidence of 1.7 %. During long-term follow-up no patient has died of stroke but one patient has had a major stroke and one a mild stroke.

**How did this compare with patients who were not operated upon?**

For a control series to compare with the surgical series 102 patients with asymptomatic bruits who were not operated upon when the bruit was first detected were followed. There were various reasons for not operating upon these patients when first seen. In the early days of the study it was unclear as to whether they should be operated upon at all. In some patients the bruit was unilateral and very soft. Certain patients did not wish to have arteriography or surgery considered while in others the patients' referring physicians did not wish to have studies performed. The control series has been followed up to 10 years. During this time 55 of the 102 patients have remained asymptomatic—(54 %). In 28 (27 %) transient cerebral ischemia developed and these patients were operated upon. Nineteen (19 %) had frank strokes usually without transient ischemic attacks from two days to four years following detection of the bruit. Thus in 47 or 46 % of the 102 patients developed during the follow-up period. When a stenotic carotid artery becomes totally occluded there is a significant incidence of acute hemiplegic stroke with its attendant mortality and morbidity.

Javid et al cite their experience with endarterectomy for asymptomatic bruits in 50 patients. Because of the high long-term mortality from causes other than endarterectomy these authors believe that is inadvisable in hypertensive patients over the age of 65 with a history of myocardial infarction. In younger patients without several risk factors, however, they recommend endarterectomy for severe internal carotid stenosis.

**What is the status of cerebral arteriography at present?**

### Next In Consultation

WILLIAM L. HASKELL, Ph.D., Clinical Assistant Professor of Medicine, Cardiology Division, Stanford University School of Medicine, Palo Alto, Calif., will discuss what's new and important regarding physical exercise after myocardial infarction, how soon exercise should be undertaken and how to determine additions to the exercise program, the benefits of exercise—and its hazards.

In the final analysis, arteriography is the definitive diagnostic maneuver necessary to establish the origin of a carotid bruit and to determine its significance as a stroke hazard. As cerebral arteriography has become increasingly safer it should be recommended more often for studying patients with asymptomatic carotid bruits.

Arteriography should probably not be recommended if the bruit is very soft and unilateral, if other considerations contraindicate surgery even if a significant lesion were found, if other conditions take priority over study of carotid lesions, and in the presence of a negative OPG test. The overall general status of each patient should be considered very carefully before noninvasive arteriography.

If the arteriograms show a significant atherosclerotic stenosis in the internal carotid artery endarterectomy may be cautiously considered. Specific indications include 1) bilateral stenosis, 2) unilateral stenosis with contralateral occlusion, 3) stenosis in the artery in the dominant hemisphere, 4) known progressive atherosclerotic lesions elsewhere in the peripheral vasculature, especially in younger patients, 5) contemplated major surgery of another sort where a hypertensive episode might well result in a stroke, and 6) so ulcerated atherosclerotic plaque.

Since no unnecessary risks should be taken appropriate measures for cerebral protection must be employed during carotid endarterectomy to avoid producing neurologic deficits. Our recommendation is the routine use of a temporary infusing shunt. Operative mortality should be below 1 % and complications no more than 2 %.

In summary, asymptomatic carotid bruits may originate in the internal carotid artery from atherosclerotic plaques which predispose to strokes in certain individuals over the age of 40. Certain recently developed noninvasive screening tests are helpful in determining the hemodynamic significance of these bruits, which ultimately require arteriography to determine precise diagnosis and significance. If hazardous lesions are demonstrated, carotid endarterectomy may be recommended for selected patients without multiple risk factors to prevent the occurrence of ischemic cerebral episodes.

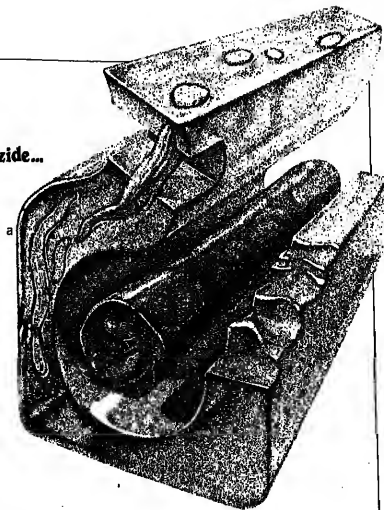


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### Control of fluid volume with hydrochlorothiazide...

Hydrochlorothiazide provides a modest antihypertensive effect through fluid volume control, and potentiates the activity of other antihypertensive drugs.<sup>1,2</sup>

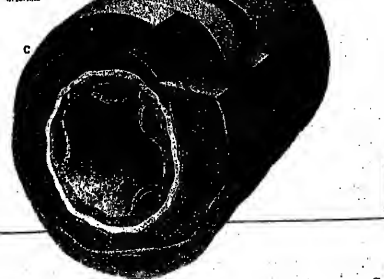
<sup>1</sup> Symbolized reduction in circulating fluid volume



### plus direct relaxation of arteriolar smooth muscle with hydralazine...

The unique action of hydralazine lowers blood pressure through direct arteriolar vasodilation to reduce peripheral resistance. The decrease in arteriolar resistance is accompanied by maintenance of regional vascular flow, which may make hydralazine particularly valuable for patients with slightly impaired renal flow.<sup>1,2</sup>

<sup>1</sup> Diagram of relaxed arteriolar



### plus control of sympathetic activity with reserpine...

Reserpine decreases blood pressure by interfering with the release of norepinephrine at peripheral sympathetic neuroeffector sites. Sympathetic inhibition also produces a central sedative effect especially helpful in management of the stress-reactive patient.<sup>1,2</sup>

<sup>1</sup> Diagram of norepinephrine depletion at sympathetic nerve ending



Please turn page for brief prescribing information.

# Only one antihypertensive provides the three preferred modes of action... Ser-Ap-Es

reserpine 0.1 mg  
hydralazine hydrochloride 25 mg  
hydrochlorothiazide 15 mg

## Three basic modes of antihypertensive action in a single tablet...

### Ser-Ap-Es®

reserpine 0.1 mg  
hydralazine hydrochloride 25 mg  
hydrochlorothiazide 15 mg

**WARNINGS**  
This fixed combination drug is not indicated for initial therapy of hypertension. Hypertension requires therapy first to the individual patient. If the fixed combination represents the dosage as determined, its use may be more convenient in patient management. The treatment of hypertension is not static, but must be reevaluated a condition in each patient warrant.

#### INDICATIONS

Hypertension. (See box warning.)  
**CONTRAINDICATIONS**  
Reserpine: Known hypersensitivity; mental depression (especially with suicidal tendencies); active peptic ulcer; ulcerative colitis; electroconvulsive therapy.

Hydralazine: Hypersensitivity; coronary artery disease; mitral valve; rheumatic heart disease.

Hydrochlorothiazide: Anuria; hypersensitivity to this or other diuretic drugs; the routine use of diuretics in a patient with a pregnant contraindicated and possibly hazardous.

**WARNINGS**  
Reserpine: Use with extreme caution in patients with a history of mental depression. Discontinue at first sign of depression, early induced depression, loss of appetite, impotence, or self-destruction. Drug-induced depression may persist for several months after withdrawal and may be severe enough to result in suicide.

MAO inhibitors should be avoided or used with extreme caution.

Hydralazine: Hydralazine may produce in a few patients a clinical picture resembling systemic lupus erythematosus. In such patients hydralazine should be discontinued unless the benefit is felt to outweigh the risk of continued antihypertensive therapy with this drug. Symptoms and signs usually regress when the drug is discontinued but relapse have been detected many years later. Long-term treatment with hydralazine may be necessary.

CAUTION: L-cell preparations and antidiabetic antihypertensive combinations are indicated to be used and particularly during prolonged therapy with hydralazine or if the patient develops any unexplained signs.

A positive antidiabetic antihypertensive combination may be necessary. The possibility of association of systemic lupus erythematosus has been reported.

Use MAO inhibitors with caution. Hydralazine: Use with caution.

In severe renal disease, in patients with renal disease, hydralazine may precipitate azotemia. Cumulative effect of the drug may develop in patients with impaired renal function.

Thiazides should be used with caution in patients with impaired hepatic function or progressive liver disease, since the metabolism of liver and electrolyte imbalances may precipitate hepatic coma.

Thiazides may be additive or potentiative of the action of other antihypertensive drugs. Potentiation occurs with blocking drugs.

Sensitivity reactions are more likely to occur in patients with a history of allergic or hypersensitivity.

The possibility of association of systemic lupus erythematosus has been reported.

**Use in Pregnancy**  
Reserpine: The safety of reserpine for use during pregnancy or lactation has not been established. Therefore, the drug should be used in pregnant patients or women of childbearing potential only when the potential benefits outweigh the risks.

Hydralazine: It is essential to the welfare of the patient that the potential benefits of the drug be weighed against the possible hazards.

Hydrochlorothiazide: The drug should be used only when the potential benefits outweigh the risks.

Hydrochlorothiazide: The drug should be used only when the potential benefits outweigh the risks.

Hydrochlorothiazide: The drug should be used only when the potential benefits outweigh the risks.

to the fetus. These hazards include fetal or neonatal jaundice, thrombocytopenia, and possibly other adverse reactions. Thiazides cross the placental barrier and appear in cord blood.

**Nursing Mothers**  
Thiazides appear in maternal breast milk.

**PRECAUTIONS**  
Reserpine: Use cautiously in patients with history of peptic ulcer, ulcerative colitis, or gallstones (biliary colic may be precipitated).

Exercise caution when treating hypertension with renal insufficiency. Use cautiously with digitalis and quinidine.

Transverse myelitis has occurred in hypertensive patients receiving reserpine preparations, but withdrawal of reserpine does not assure that circulatory instability will not occur in such patients.

Hydralazine: Use cautiously in patients with a history of peptic ulcer, ulcerative colitis, or gallstones (biliary colic may be precipitated).

Exercise caution when treating hypertension with renal insufficiency. Use cautiously with digitalis and quinidine.

Transverse myelitis has occurred in hypertensive patients receiving reserpine preparations, but withdrawal of reserpine does not assure that circulatory instability will not occur in such patients.

Hydrochlorothiazide: Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals. Signs and symptoms of electrolyte imbalance (hypokalemia, hypochloremia, hypomagnesemia, hypocalcemia, hypophosphatemia, hypoproteinemia, hypokalemia, hypochloremia, hypomagnesemia, hypocalcemia, hypophosphatemia, hypoproteinemia) should be watched for.

Hydrochlorothiazide: Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals.

## all the medication many patients need...

## Ser-Ap-Es®

reserpine 0.1 mg  
hydralazine hydrochloride 25 mg  
hydrochlorothiazide 15 mg

Current clinical practice stresses the importance of achieving control of basic homeostatic mechanisms as the key to control of high blood pressure.

Indeed, the landmark VA studies utilized three basic drugs to establish control of three homeostatic mechanisms. These were control of fluid volume with hydrochlorothiazide, control of sympathetic activity with reserpine, and control of arteriolar tone with hydralazine. The study of 1987 concluded that most hypertensive patients could be successfully controlled with combinations of these basic drugs.

Only Ser-Ap-Es provides control of these basic mechanisms—employing the same antihypertensives used in the VA studies. (In the VA studies, Ser-Ap-Es itself was not used. However, all the components of Ser-Ap-Es were used in varying combinations.)

And when the dosage of each component corresponds to the dosage prescribed by individualized titration,

Ser-Ap-Es may prove more convenient and economical. Many patients will need no other medication.

**Note:** Use Ser-Ap-Es cautiously in patients with advanced renal damage or cerebrovascular accident. Discontinue at first sign of mental depression.

**References**  
1. Russell, R. P. Hypertension. In: Harvey AM, Johns RJ, Owens AH, et al (eds). *The Principles and Practice of Medicine*, 2nd ed. New York: Appleton-Century-Croft, 1973, pp 331-334.  
2. Gilson, W. Drugs for arterial hypertension. In: *Medical W (ed) Drugs of Choice* 1972-1973. St. Louis, The CV Mosby Co, 1972, p 330-333.  
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4. Fink DC. Hypertension. A continuing disease. *Can Med Assoc J* 1972; 106:242-243.  
5. Effect of treatment on mortality in hypertension. Results in patients with diastolic blood pressure averaging 115 through 130 mm Hg. *Joint Intensive Treatment Cooperative Study Group in Antihypertensive Agents*. *JAMA* 202:1038-1034, 1967.  
6. Effects of treatment on mortality in hypertension. Results in patients with diastolic blood pressure averaging 90 through 114 mm Hg. *Intensive Treatment Cooperative Study Group in Antihypertensive Agents*. *JAMA* 213:1451-1452, 1970.

asthma, arthritis, rash, dryness of mouth, dizziness, headache, depression, anorexia, epistaxis, purpura and other hematological reactions; impotence or decreased libido; dysuria; muscular aches, convulsions; injection weight gain; breast engorgement; prostatic hypertrophy; gynecomastia; rarely water retention with edema in hypertensive patients.

**Hypertension Complications:** headache, palpitations, anorexia, nausea, vomiting, diarrhea, tachycardia, angina pectoris, loss of vision—nasal congestion, burning lacrimation, conjunctivitis, peripheral neuritis, evidenced by numbness, numbness, and tingling, edema; dizziness, tremors; muscle cramps; psychotic reactions characterized by depression, disorientation, or a psychotic picture (including mania, irritability, psychosis, etc.).

**Hydrochlorothiazide:** Gastrointestinal: anorexia, gastric irritation, nausea, vomiting, constipation, diarrhea, constipation, jaundice (intrahepatic cholestatic), pancreatitis. Central Nervous System: dizziness, vertigo, parosmia, headache, numbness, depression, fatigue, weakness, lethargy, irritability, nervousness, sensitivity—purpura, photosensitivity, Stevens-Johnson syndrome, and other hypersensitivity reactions. Hematologic: leukopenia, agranulocytosis, thrombocytopenia, aplastic anemia. Cardiovascular: orthostatic hypotension may occur and may be potentiated by alcohol, barbiturates, or narcotics. Other: hyperglycemia, glucose, hyperkalemia, muscle aches, weakness, restlessness. Whenever adverse reactions are moderate or severe, reduce dosage or withdraw therapy.

**Dosage**  
As determined by individual titration (see box warning).

Usual dosage is 1 or 2 tablets t.i.d. For maintenance, adjust dosage to meet patient requirements. When necessary, more potent antihypertensives may be added gradually if dosage reduced by at least 50 percent.

**Tablets** (dark salmon pink, dry-coated, 15 mg hydralazine hydrochloride, 25 mg reserpine, 15 mg hydrochlorothiazide, and 15 mg of 100 and 1000).

Consult complete literature before prescribing.

**CIBA Pharmaceutical Company**  
Division of Ciba Limited, Summit, New Jersey 07901

12400 11

CIBA

# The Pseudo-ulcer



## Ulcer-like symptoms: no G.I. pathology

The patient is convinced it's an ulcer. However, symptoms are not quite typical, and x-ray findings are negative. These findings and the results of additional diagnostic procedures exclude an organic basis for the patient's complaints. A diagnosis of "upper functional gastrointestinal disorder" is made, which is supported by the fact that episodes of painful symptoms coincide with episodes of excessive anxiety, as indicated by the history.

It may be useful to explain to the patient the mechanism by which emotional upset normal G.I. functioning, resulting in hypersecretion and hypermotility and thus causing such symptoms as nausea and epigastric pain. In upper functional gastrointestinal disorders, counseling by the primary physician can often help the patient to understand how excessive anxiety may cause flare-ups of G.I. symptoms.

A disproportionate number of patients seen by the general practitioner suffer from functional disorders, as do more than half of those seen by the gastroenterologist. Where milder cases may respond to counsel-

ing alone, if symptoms are severe and disabling to any degree, a suitable regimen may include medication to relieve the symptoms and the excessive anxiety that often provokes these distressing symptoms. In these cases, Librax as an adjunct can greatly contribute to the course of therapy. Its dual action can offer relief of both painful symptoms and excessive anxiety, because each capsule contains 5 mg chloridazepoxide HCl and 2.5 mg cimetidine HCl. The anxiolytic action of Librax® (chloridazepoxide HCl) makes Librax exceptional among drugs for certain gastrointestinal disorders associated with excessive anxiety; the cimetidine hydrochloride (Zantac®) component firm has dependable antisercretory-antispasmodic action. Dosage is flexible; it may be adjusted according to your patient's requirements within the range of 1 or 2 capsules three or four times daily, up to 8 capsules daily in divided doses.

### An adjunct in anxiety-related upper functional G.I. disorders

**Librax®**  
Each capsule contains 5 mg chloridazepoxide HCl and 2.5 mg cimetidine HCl.

\*Rome HP, Brameck TJ. Orientation and mechanism of functional disorders; clinical pharmacology correlation, chap. 155, in *Gastroenterology*, edited by Bosman HL, Philadelphia, WB Saunders Company, 1965, p. 1116.

ness, ataxia and confusion may occur, especially in the elderly and debilitated. As with all anticholinergic drugs, an inhibitory effect on lactation may occur. Precautions: In elderly and debilitated, limit dosage to smallest effective amount to preclude development of ataxia, drowsiness or confusion (not more than two capsules per day). Though generally not recommended, if combination therapy with other psychotropics seems indicated, carefully consider individual pharmacologic effects, particularly in use of potent sedative drugs such as MAO inhibitors and phenothiazines. hepatic function. Paradoxical reaction of impaired renal or stimulation and acute vagi have been reported in psychiatric patients. Employ usual precautions in treatment of anxiety states with evidence of impending depression; suicidal effects on blood coagulation have been reported with variable in patients receiving the drug and oral anticoagulants; relationship has not been established. Adverse Reactions: No side effects or manifestations not seen with either compound alone have been reported with Librax. When chloridazepoxide hydrochloride is used alone, drowsi-

Before prescribing, please consult complete product information, a summary of which follows:

**Indications:** Symptomatic relief of hypersecretion, hypermotility and anxiety and tension states associated with organic or functional gastrointestinal disorders and as adjunctive therapy in the management of peptic ulcer, gastritis, duodenitis, irritable bowel syndrome, spastic colitis, and mild ulcerative colitis.

**Contraindications:** Patients with glaucoma, prostatic hypertrophy and benign bladder neck obstruction; known hypersensitivity to chloridazepoxide hydrochloride and/or cimetidine bromide.

**Warnings:** Caution patients about possible combined effects with alcohol and other CNS depressants. As with all CNS-acting drugs, caution patients against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving). Though physical and psychological dependence have rarely been reported on recommended doses, use caution in administering Librax to alcoholics or those who might be known addiction-prone individuals or those who might increase dosage, withdrawal symptoms (including convulsions), following discontinuance of the drug and similar to those seen with barbiturates, have been reported. Use of any drug in

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Nutley, New Jersey 07110

The Only Independent Weekly Medical Newspaper in the U.S.

# Medical Tribune

and Medical News  
Published by Medical Tribune, Inc.

## ...Lest We Celebrate Prematurely...

Continued from page 1

regulation, of hypocrisy in avoidance of real issues, we must be forgiven our skepticism, if not cynicism, as to what will now happen. While we admire the courage of the government officials who now try to move forward as good doctors, good officials and good citizens should do in the public interest, we fear for both their careers and for the outcome of their constructive initiatives.

It is not too hard to predict that legal and/or legislative grounds will be found or provided to nullify an action that is as welcome as it is belated. For 35 years the public has been bamboozled into the belief that substantive actions were being taken in protection of their health. The public does not realize that medicals, no matter how beneficent in a therapeutic application, would rarely if ever be marketed if they combined the high addictive potential with the carcinogenicity, the cardiac, cerebral and hepatic-toxicity of alcohol.

The public does not know that alco-

hol and tobacco, or either one alone, year in and year out kill more people and do more damage than all other drugs combined and do so to such an extent as to constitute in themselves the major preventable causes of death in the United States, as it does in most "civilized" societies.

How was the public to know the truth and the whole truth about a drug which enmeshes over nine million Americans and plagues the lives of scores of millions in their families? Was there a conspiracy of silence? How can we understand the inaction of FDA officials of the past, the lack of adequate and persistent hearings in our houses of Congress, the relative apathy of the editorial writers of even our greatest newspapers and the mass media as a whole?

As long as news and facts of the monumental damage caused by alcohol and tobacco to millions of Americans continues to be a "no-no," so long will we fail to face up to our major preventable health problems.

## ...A Landmark Action

THE PRESENT LANDMARK ACTION of the FDA could be the most important single act of that body in the 35 years since it transferred the liquor-labeling authority to the Bureau of Alcohol, Tobacco and Firearms of the Treasury Department. It is not relevant, it can and it should save more lives, prevent more physical damage, reduce more social derangements than all prior actions of the FDA to respect to all drugs. It can and it should reduce the flood of diversionary attacks on doctors and their drugs and restore true public health perspective. It can and it should replace the shadow of regulation with the substance of public health protection in respect to all food and drugs.

Regulation must encompass not only safe and effective medications and foods but also these most toxic of substances which, through political and legislative legitimization, have been classified illogically, unscientifically and dishonestly as a "food," in the case of alcohol, and an

an "agricultural product" in the case of tobacco. There has been an idiosyncrasy in respect to the drug lysozyme that has been whittled up about marijuana and medicine—unless it was used as a "cure" for the virtual default of protective government action in respect to alcohol and tobacco, the two major problems of drug addiction and drug damage, somatic, psychic, and social.

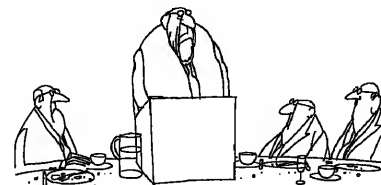
We have noted editorially that the major contributions of recent Republican Administrations in the health field was the upgrading of the health agencies leadership and manpower with the appointments of men of brilliance and proven achievement, as Dr. Theodore Cooper, Assistant Secretary for Health; men of competence and proven background such as Dr. Alexander M. Schmidt, the FDA Commissioner; Dr. Richard Crout, Director of the Bureau of Drugs, and the advancement of such men as Sam D. Finc. It is now clear all these men share the quality of integrity.

## For Public Health Perspectives...

SINCE THE FOUNDING OF MEDICAL TRIBUNE, one of the primary elements in its credo was the need for public health perspective—to set our health priorities to accord with the incidence of death and disability. This made essential recognition that the two greatest potentials for reducing morbidity and mortality lay in reducing addiction to alcohol and tobacco. Beginning with its earliest issues, MEDICAL TRIBUNE pioneered in addressing safety and environmental pollution. These issues have now come from the

backwaters of disregard to the mainstream of American consciousness with legislation and regulations for safer cars and a better ecology. Virtually no week or month has passed in which MEDICAL TRIBUNE has not also pointed the problems in the field of alcoholism and cigarette smoking. At long last a government regulatory agency has taken what is a first, but all-essential, step in an area where regulation can save scores of thousands of lives with simple, intelligent initiatives and non-prohibition, non-constructive, constructive programs.

MEDICAL SOCIETY DINNER



"... Had I known beforehand, I could have treated that chicken..."  
© 1975 Medical Tribune, Inc.

## ...Lest We Celebrate Prematurely...

NOW THAT THE BATTLE IS JOINED, we look to our leaders in Congress, to all members of the Senate and the House, to all officials in government to "show their colors." We fear that behind the scenes lobbying and pressures will be brought to bear on all branches of government. What is needed now is a mobilization of legislative as well as government leaders, of the scientific as well as the general community to support the FDA and, regardless of where the responsibility resides for the labeling, the advertising and the education of the public in respect to alcoholism, that it be honestly discharged and that effective action in respect to alcohol no longer be the exclusive province of vested, political and other interests.

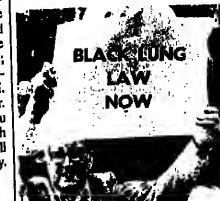
MEDICAL TRIBUNE has never opted

for prohibition. On the contrary, it has always favored a wide latitude of freedom of action. MEDICAL TRIBUNE has never opted for restrictive or prejudiced regulatory action. MEDICAL TRIBUNE has never opted for an unrealistic "informed consent" but rather for an intelligently and humanely informed public. We want no compulsory prohibition, no prejudiced, unrealistic regulation. We do want an informed public and realistic programs of action. When a problem is not honestly presented, there can be no constructive solution and, in the absence of a reasonable program of action, alcohol will continue to take its toll in the tens of millions—of its victims, of their families, and of the community of which they are a part. A.M.S.

## LETTERS TO TRIBUNE

### Black Lung Relationships

Your picture (MT, Oct. 15) struck me as being ironic in that the man holding the sign was demanding legislation and concomitantly smoking a big cigar. OLIVER P. CAMPBELL, M.D. Colorado Springs, Colo.



interested in work done on the International health front and W.H.O. in preventive medicine.

I am a psychiatrist but also a musician and greatly interested in art, film, dance, etc.—both intrinsically and for their value in therapy. RUTH SCHNAPPER RINDER, M.D. Milwaukee, Wis.

### On the One Hand...

Your editorial [On the One Hand... (MT, Sept. 24)] was excellent. Unfortunately, I think it should have been in the New York Times rather than the Medical Tribune. One problem is that we are all very articulate in commenting on our problems in medical journals, but these comments never get into the lay press. WARREN D. BOWMAN, JR., M.D. Billings, Mont.

### Beg Pardon

An advance notice (MT, Nov. 12) about an article in SEXUAL MINDNESS TOXIC (MT, Nov. 19) implied that Dr. Samuel B. Hadden achieves a heterosexual commitment in 80 per cent of the homosexual males whom he treats. The article itself correctly reported that commitment to a heterosexual life was "achieved in 30 to 40 per cent of selected patients." Our apologies to Dr. Hadden.

### von Karajan

I read with great interest Dr. Sackler's interview with Herbert von Karajan on "Music and Medicine"... I am, also





# "Let me tell you about the medicine I'm going to prescribe."

## TALKING OVER VALIUM®(diazepam) THERAPY WITH YOUR ANXIOUS PATIENT.



A patient often benefits by a greater understanding of his treatment program. You may find it helpful to make your patient aware that the purpose of therapy with Valium is to help reduce discomforting and disabling symptoms of excessive psychic tension and anxiety. It is beneficial for him to understand that much of his tension and anxiety can be relieved by your reassurance and counseling, and that these measures can do more than anything else to help him cope with his basic problems. The patient is reassured in knowing he can expect his medication to help him avoid feeling overwhelmed by his symptoms.

And it's also good for him to realize that he will be taking Valium only as long as he needs it. Your expressed confidence in the medication prescribed, and the positive atmosphere in which therapy is given and accepted, work to the patient's advantage.

Selection of a dosage regimen is an important consideration when Valium (diazepam) is prescribed, and dosage should be individualized to achieve maximum beneficial effect. If the patient understands clearly when and how much to take, and if he knows why it's to his benefit to follow the regimen closely, the chances are better that he will take the medication precisely as directed. That should help avoid missed doses and discourage taking too much or too little medication — all of which can have an undesirable effect on the management of the patient's condition.

*"It's important that you follow my directions closely."*

*"I'll see you again the week after next and we'll see how you're making out."*

Your patient is often likely to feel reassured when you talk about seeing him again to check his progress. A planned visit evidences your continued interest and affords the patient an opportunity to report improvement he has made and to relate whatever continuing or additional difficulties he may be experiencing. It's also a chance for him to describe his response to therapy with Valium.

During follow-up visits, as your patient talks about his medication and about its effects on his symptoms, he will provide the kind of information that will be of great help in evaluating total therapy, adjusting the dosage of Valium, or discontinuing the medication entirely if that seems indicated.

# Valium® (diazepam) <sup>®</sup>

2-mg, 5-mg, 10-mg scored tablets <sup>®</sup>

*for individualized treatment of psychic tension*



Please see the following page for a summary of product information.





# Valium® (diazepam)

2-mg, 5-mg, 10-mg scored tablets

Prompt, effective action. Valium (diazepam) works rapidly to relieve pronounced psychic tension in patients overreacting to stress and in psychoneurotic patients.

Before prescribing, please consult complete product information, a summary of which follows:

**Indications:** Tension and anxiety states; somatic complaints which are concomitants of emotional factors; psychoneurotic states manifested by tension, anxiety, apprehension, fatigue, depressive symptoms or agitation; symptomatic relief of acute agitation, tremor, delirium tremens and hallucinosis due to acute alcohol withdrawal; adjunctively in skeletal muscle spasm due to reflex spasm to local pathology; spasticity caused by upper motor neuron disorders; athetosis; stiff-man syndrome; convulsive disorders (not for sole therapy).

**Contraindications:** Known hypersensitivity to the drug. Children under 6 months of age. Acute narrow angle glaucoma; may be used in patients with open angle glaucoma who are receiving appropriate therapy.

**Warnings:** Not of value in psychotic patients. Caution against hazardous occupations requiring complete mental alertness. When used adjunctively in convulsive disorders, possibility of increase in frequency and/or severity of grand mal seizures may require increased dosage of standard anticonvulsant medication; abrupt withdrawal may be associated with temporary increase in frequency and/or severity of seizures. Advise against simultaneous ingestion of alcohol and other CNS depressants. Withdrawal symptoms (similar to those with barbiturates and alcohol) have occurred following abrupt discontinuance (convulsions, tremor, abdominal and muscle cramps, vomiting and sweating). Keep addiction-prone individuals under careful surveillance because of their predisposition to habituation and dependence. In pregnancy, lactation or women of childbearing age, weigh potential benefit against possible hazard.

**Precautions:** If combined with other psychotropics or anticonvulsants, consider carefully pharmacology of agents employed; drugs such as phenothiazines, narcotics, barbiturates, MAO inhibitors and other anti-

depressants may potentiate its action. Usual precautions indicated in patients severely depressed, or with latent depression, or with suicidal tendencies. Observe usual precautions in impaired renal or hepatic function. Limit dosage to smallest effective amount in elderly and debilitated to preclude ataxia or oversedation.

**Dosage flexibility.** Scored Valium 2-, 5-, and 10-mg tablets give you dosage flexibility no tranquilizer capsule can match.

**Side Effects:** Drowsiness, confusion, diplopia, hypotension, changes in libido, nausea, fatigue, depression, dysarthria, jaundice, skin rash, ataxia, constipation, headache, incontinence, changes in salivation, slurred speech, tremor, vertigo, urinary retention, blurred vision. Paradoxical reactions such as acute hyperexcited states, anxiety, hallucinations, increased muscle spasticity, insomnia, rage, sleep disturbances, stimulation have been reported; should these occur, discontinue drug. Isolated reports of neutropenia, jaundice; periodic blood counts and liver function tests advisable during long-term therapy.

**Dosage:** Individualize for maximum beneficial effect. **Adults:** Tension, anxiety and psychoneurotic states, 2 to 10 mg b.i.d. to q.i.d.; alcoholism, 10 mg t.i.d. or q.i.d. in first 24 hours, then 5 mg t.i.d. or q.i.d. as needed; adjunctively in skeletal muscle spasm, 2 to 10 mg t.i.d. or q.i.d.; adjunctively in convulsive disorders, 2 to 10 mg b.i.d. to q.i.d. **Geriatric or debilitated patients:** 2 to 2½ mg, 1 or 2 times daily initially, increasing as needed and tolerated. (See Precautions.) **Children:** 1 to 2½ mg t.i.d. or q.i.d. initially, increasing as needed and tolerated (not for use under 6 months).

**Supplied:** Valium® (diazepam) Tablets, 2 mg, 5 mg and 10 mg—bottles of 100 and 500; Tel-E-Dose® packages of 100, available in trays of 4 reverse-numbered boxes of 25, and in boxes containing 10 strips of 10; Prescription Paks of 50, available singly and in trays of 10.

Roche Laboratories  
Division of Hoffmann-La Roche Inc.  
Nutley, New Jersey 07110

Wednesday, December 17, 1975

MEDICAL TRIBUNE

17

## One Man...and Medicine

ARTHUR M. SACKLER, M.D.  
International Publisher, Medical Tribune



### Say It Again, Sam\*

**O**KAY, SO IT ISN'T *Poor Richard's Almanac*. But how many Ben Franklins do we really have? Statesman, scholar, printer, publisher, draftsman of the Declaration of Independence, a bon vivant, full of wit and wisdom. In this day of specialization, when politicians are politicians with little wit and debatable wisdom, when our diplomats are schooled more in rhetoric than logic and their inventions relate more to what they see, when our scientists number few statesmen and less bon vivants, thank goodness we still have a few men who specialize in pungent commentaries on the current scene—with wit and wisdom.

Sam Levenson is one such, and I have asked for his assistance in bringing to you a number of his observations which are related to the field of medicine, psychology and sociology. Sam said "Okay," so here we go. The captions are by *Man...and Medicine*, the commentaries, incisive, caustic, incisive and insightful, are by Sam Levenson.

**On prognosis in the aged**  
I hope I'm really sick. I'd hate to feel like this if I'm well.

**On taking medical history**  
My boy, I was sick before you were born.

**On medical progress**  
If medical science has made so much progress in the last 50 years, how come I feel so much better 50 years ago?

**On illness**  
I beg your pardon, does the ringing in my ears annoy you?

**On patient recall**  
At what point do you become an old-timer? You already are if you can remember:

When castor oil was the wonder drug.

When dope was what they called a less-than-bright youngster.

When doctors made house calls.

**On Genetics**  
Insanity is hereditary... you can get it from your children.

**On IQs**  
It has been said that a genius is a stupid kid with very happy grandparents.

**A material glossary**  
1. High-IQ child: A kid who says dirty words earlier than other kids.

2. Autosuggestion: The parental compulsion to jump into (or in front of) an auto and get a way from it all.

3. Hallucinations: See visions of kids without running noses.

4. Self-expression: In a child, any act which cannot be explained rationally.

5. Siblings: Children of the same parents, each of whom is perfectly sane until they get together.

6. Sex music: A husband who wants more children.

**On child psychology**  
Child punishment, current American-style, runs somewhat along these lines:

About 6:15 pm, the mother gets very dramatic, turns to the child and says, "Go to your own room." He's got a television set there; he's got his own refrigerator; he's got a train set that goes through the other people's apartment and back again; they send his dinner in to him, leave him for the evening with an 18-year-old baby sister—and he's being punished. His father didn't live like that on his honeymoon!

**On the rights to privacy**  
There is a new rule which forbids parents from walking into their kid's room without knocking. The kid walks around with the Bill of Rights in his dinger and knows what he is entitled to. He's been advised by his four-year-old civil rights lawyer (the kid next door) that his tense entitles him to privacy.

**On physical activities**  
You can't let a kid walk. He might get hit by a snowflake and have a concussion. So the mother drives the child to the corner and keeps his lovely warm in the car until she can deposit him into the warm bus. By the time he gets to college he will need a course in remedial walking.

**Paradoxical but true:** The school spends \$20,000 for a bus so the kids don't have to walk, until then spends \$200,000 for a gymnasium so the kids can get exercise.

**On prejudices**  
Some people are so prejudiced they don't even listen to both sides of a phonograph record.

Disliking people requires a reason; loving doesn't.

The difference between a conviction and a prejudice is that you can explain a conviction without getting angry.

**On relative values**  
Papa was so impressed by a newspaper story reporting that Rin Tin Tin earned over \$200,000 a year, "And we have to have children," Papa lamented.

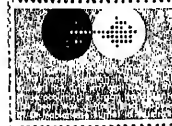
**On initiatives**  
Papa helped each of us get started on the road to success: "Remember, my son, if you ever need a helping hand, you'll find one at the end of your arm. And remember, too, if you want your dreams to come true, don't sleep.

**On inflation**  
"A penny for your thoughts" is now 50 dollars an hour with the psychoanalyst... An apple a day costs more than eating the doctor. And if the doctor tells you you're sound as a dollar, you're really in trouble.

**On orientation**  
Who said Columbus was an Italian? He was the first real American. When he started out, he didn't know where

## Medicine on Stamps

Frank Macfarlane Burnet



Born in Australia in 1899, he received his M.D. from Melbourne University, joined Royal Melbourne Hospital, then decided to devote his life to research. After several years of study in England, he returned to Australia to stay. In 1942 he was elected a Fellow of the Royal Society and, in 1947, he received the Society's Royal Medal for his distinguished work in bacteriophages, viruses and immunity. His clonal selection theory of acquired immunity led to a Nobel Prize in Medicine in 1960.

Test: Dr. Joseph Kler  
Stamp: Minkus Publications, Inc., New York

he was going. When he got here, he didn't know where he was. When he got back, he didn't know where he'd been. And he did the whole thing on borrowed money.

**On nutrition**  
We have the best-fed garbage cans in the world, filled to overflowing with food that has been stabbed, cut, tasted and rejected. We throw away the skin, the fat, the gristle, the bone.

**On anorexia**  
No one ever had to urge us to eat. (With our appetites, if you had put sugar on a fly it would have tasted like a lullaby.)

**On stimulating the appetite**  
My elegant brother Mike made Mama's left-overs sound gourmetish by

giving them French names: hamburger accumulé, liver roulé, ragout prolongé beef rotoureux, salmon rejuvené, eggs renaissance.

**On surgery and art**  
Mama bought a fresh whole chicken. Her daughter's chicken has been eviscerated, dismembered, neatly disjointed, frozen, and all its organs sorted out and filed in plastic see-through bags. The young housewife has been spared the bloody ordeal of chicken surgery. Chicken can now be bought in parts. Anyone can create his own version of a chicken out of a do-it-yourself chicken kit. Put together two heads, one eye, three breasts and four feet, add a mandolin, and you've got yourself an original poultry Picasso.

**Prescribed for Waiting Rooms**  
You sure can say *Say That Again, Sam*. We strongly prescribe several copies for the practicing physician's waiting room. We found the book a stimulant without side effects and a tranquilizer which sharpened the mind. Above all, patients under tension may very well appreciate its encouraging aspects and new perspectives on life. If your bookstore doesn't have it, let the Pocket Books people know you want it. Not all your medicine has to come in capsules or ampules. Here is a healthy treatment in inexpensive book form.

\*Levenson, Sam: You Can Say That Again, Sam; Pocket Books, 1 West 39th Street, New York, N.Y. 10018.

**EPICRAMS—Clinical and Otherwise**  
The real scientist...is ready to bear privation and, if need be, starvation rather than let anyone dictate to him which direction his work must take. Albert Szent-Gyorgyi In Science Needs Freedom [World Digest, 1943]

## Boost for Rabies Vaccine Seen in 'Interferon Inducer'

Medical Tribune Report  
SALT LAKE CITY—University of Utah researchers have developed a technique that promises to increase the effectiveness of rabies vaccine. The method involves stimulating the release of interferon at the site of the rabies wound.

Dr. Burton Janis, Associate Professor of Medicine and Assistant Professor of Microbiology, and Maurice W. Harmon, a doctoral candidate in microbiology, report that mice exposed to rabies and treated with vaccine alone had four times the death rate of mice treated with a combination of vaccine and poly-I:C, an "interferon inducer."

**Vaccine Blockage**  
"Human serum prevents the rabies virus from replicating until the body's own antibody response is activated," says Dr. Janis. "But the serum can also stall the body's own immune response by blocking the action of the vaccine, by blocking booster shots of vaccine. This is why booster shots of vaccine are necessary. We believe the use of an interferon inducer, with the vaccine may be just as effective or more effective than serum and vaccine, with the added advantage that it would eliminate the need for booster shots."



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## Theophylline Monitored in Bronchospasm

Medical Tribune Report

ANAHEIM, CALIF.—To avert severe toxic reactions associated with the intravenous use of aminophylline in the treatment of acute bronchospasm, levels of serum theophylline should be carefully monitored, according to a report presented here at the 41st Annual Scientific Assembly of the American College of Chest Physicians.

Although aminophylline (a salt of the naturally occurring theophylline) has proved very effective in the treatment of acute bronchospasm, patients who receive it intravenously are sometimes subject to cardiac arrhythmias, seizures and even death, said Dr. Richard A. Matthay of Yale University School of Medicine. Control of asthma

with aminophylline is best when serum theophylline levels are about 10 micrograms/milliliter while adverse effects are most common when the dosage is above 20 mcg/ml.

### Chromatographic Assay

High pressure liquid chromatographic assay proved to be a rapid and practical method for monitoring serum theophylline levels in about 23 patients scheduled to receive intravenous aminophylline. In five patients with initial serum theophylline concentrations less than 10 mcg/ml, aminophylline dosage was calculated to raise the level to the accepted therapeutic range, said Dr. Matthay. Although they responded to therapy without ill effects, three out of

four patients who received the usual dosage of aminophylline without having serum theophylline levels determined showed toxic symptoms.

Dr. Matthay pointed out also that the patients' prior history of aminophylline use correlated very poorly with theophylline levels and that continuous aminophylline therapy administered in a standardized dose of 0.9 mcg/kg/hour or less produced variable, and frequently excessive, serum concentrations of theophylline.

Based on his studies, Dr. Matthay proposes that carefully relating intravenous aminophylline dosage to serum theophylline may improve the outcome of therapy with that drug.

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**Ask Janeway**  
How can one open a Swiss bank account? Are there U.S. taxes on interest? Is such an account a good hedge against inflation?

Iowa Physician

Writing to the New York branches of the Swiss banks is one way. Whatever you deposit over there should be put on the table after tax savings have cleared IRS audits. All interest received is taxable, but your tax bill won't be much from a Swiss passbook because your interest will be so little. There are some worse hedges against inflation, but I can't think of them.

Send your questions on finance, investments, taxes to Janeway, MEDICAL TRIBUNE, 880 Third Avenue, New York, N.Y. 10022

Wednesday, December 17, 1975

## Tribune Economic Analysis



**On Relocating  
The Urban Poor  
From Sick Cities**

By ELROY JANEWAY  
Consulting Economist

The urban crisis has featured to the point of precipitating a first-class financial panic. The time has come to start thinking about new solutions to the problem instead of just continuing to throw more money at the same victimized people.

Provisionally, a different approach has been suggested by Dr. Bruno Bettelheim, the pioneering practitioner of reclamation techniques for the psychologically wounded at the University of Chicago. In an interview with me in 1969, Dr. Bettelheim pointed out that the American states boasting the biggest beckoning frontiers are hampered by having the smallest populations. Conversely, the smallest states are burdened with the greatest population congestion.

Until now, people with median incomes or better have been the ones taking advantage of opportunities to relocate from the country's congested areas, which are poor in natural resources, to its rich, undeveloped inland empires. Dr. Bettelheim's thinking calls for large-scale redistribution of the population to alleviate social pressures.

Picking up families on welfare in New York and just transplanting them en masse to New Mexico is not the answer. But asking what needs to be done to prepare the virgin lands of the West to absorb a planned population shift is the practical approach to a workable answer. Meanwhile, it makes no sense to waste dollars in keeping New York populated with slum dwellers while not using dollars to prepare New Mexico to overcome the disadvantages of being underpopulated. Bettelheim's concept targets the largest states that are hampered by the smallest population as the "sociological soil" in which to plant "seed money" for the building of new communities. A plan for orderly relocation offers the only long-term hope for the sick cities.

### Ask Janeway

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Wednesday, December 17, 1975

## Our Readers Write about the President's Cold Dr. Lasagna's Letter and Dr. Sackler's View

Continued from page 1

only the recommended symptomatic treatment and more often than not, the patients have to have subsequent visits because they become sicker and require antibiotics and sometimes hospitalization.

It is very reassuring and encouraging to me that a physician of Dr. Lasagna's reputation and expertise has spoken out on this matter.

WILLIAM G. GILLIES, M.D.  
Galena, Ill.

THE WHITE HOUSE  
WASHINGTON  
November 18, 1975

Dear Harry:

Thank you for the most interesting yet controversial aspect of the President's recent cold.

Sincerely,

William M. Lasagna, M.D.  
Rear Admiral, MC, USN  
Physician to the President

Dr. Harry Henderson  
Editor-in-Chief, Medical Tribune  
880 Third Avenue  
New York, New York 10022

I agree wholeheartedly with Dr. Lasagna! The FDA and HEW doctors should treat people, not computers.

DONALD E. J. LINDBERGER, M.D.  
Milwaukee, Wis.

I refer to "colds" as "flu syndromes." These present with varying combinations of rhinitis, pharyngitis, adenitis, bronchitis, otitis media, myalgia, and malaise. Varied bacterial and non-bacterial complications are frequent. When bacterial complications are likely, I always prescribe an antibiotic—usually tetracycline or erythromycin (or other antibiotics as specific treatment for various identified or suspected organisms, e.g., penicillin for Strep. infections).

When cough is present, usually this means that bronchitis is present, in the absence of findings to the contrary. I always treat bronchitis with an antibiotic—my first choice being tetracycline. It is my distinct impression that antibiotic therapy shortens the course of bronchitis associated with the "flu syndrome" in most cases.

There is no doubt in my mind that the expected benefits of antibiotic therapy far outweigh the possible disadvantages of antibiotic side-effects which are seldom serious with the exception of penicillin sensitivity reactions which can be quite serious. Penicillin is actually in common use, due to associated sensitivity reactions.

I prescribe mycostatin vaginal tablets for "as needed" usage for all mature females on antibiotic therapy for as much as 10 days or longer—due to

the high incidence of monilial vaginitis in these patients.

LOYO C. BRANNON, M.D.  
Athens, Ga.

I concur one thousand per cent with the fact that generally speaking, patients with complications associated with "colds" visit physicians and therefore the majority do require the use of antibiotics. Possibly we should listen more to practicing physicians rather than "preaching" physicians.

ALLEN P. JETER, M.D.  
Winnabro, S.C.

In January, 1974, I sent the enclosed pamphlet to all my patients and left copies in my office, available to anyone. My purpose was to provide information that would allow patients to care for themselves and become aware of those situations in which antibiotics might be of some value.

From discussions with my two associates and other colleagues in this area, I think that I can conclude that most patients in our practices are not seen for uncomplicated coryza and if seen for that problem are not treated with antibiotics. When needed, tetracycline hydrochloride and erythromycin stearate are the antibiotics we most frequently use and the selection is usually made on the basis of several factors, not the least of which is individual physician preference.

Antibiotic aversion, like adverse drug reaction, is probably a byproduct of statistical imagination based on the extrapolation of unreliable or incomplete studies.

Finally, I would like to thank you for your many valuable contributions in society.

AUGUSTUS A. AQUINO, M.D., P.A.  
Helixville, Md.

May I say "bravo" for both Dr. Lasagna and Dr. Sackler?

As a solo private practitioner for 24 years, I haven't really had time to write letters in editors very often, but rather have used my time to make decisions about treating patients.

I agree completely with the statements made by both men.

CHARLES L. CUNIFF, M.D.  
Jersey City, N.J.

A tribute in your TRIBUNE to Professor Louis Lasagna for his astute observation that even the President does need treatment. A patient taught me how to treat a cold a long time ago: "If you had given me that penicillin yesterday, I wouldn't be sick today, so I'm not going to pay you for today."

We would have less trouble with critics if they would spend some time treating patients.

CLOYE H. DOUGHERTY, M.D.  
Hopewell, Va.

I heartily agree with Professor Lasagna's position on the "not so common cold."

Dr. Lukesh did as so many of us in general practice have been doing for years since the advent of antibiotics,

## Dr. Lasagna Writes on Colds and Antibiotics

March 27, 1974

Dear Arthur:

One of the most consistently raised points in the current discussion about overprescribing of drugs is the alleged prescribing at a spinal reflex level of antibiotics for "the common cold." It is repeatedly said that in surveys of doctors in practice, a very high percentage of patients who come to the doctor's office for "the common cold" receive an antibiotic.

On the face of it, this seems reprehensible. On reflection, however, it occurs to me that most patients do not visit a doctor's office, and pay good money, for advice about uncomplicated coryza. I suspect, instead, that most patients with upper respiratory complaints go to see doctors suffering from a combination of cough, stuffed nose, post-nasal drip, swollen glands in the neck, earache, etc.—in other words, from secondary bacterial complications of the common cold. If this is the case, then the prescribing of an antibiotic is not wrong; rather, the question is only: what antibiotic would be best? I ask that you print this letter in Medical Tribune to solicit from your readers some facts bearing on the statements I have just made. If I am wrong, then the doctors of this country deserve the severe criticism they are receiving from many quarters at present. If I am right, then the doctors are practicing good medicine, and it is the critics who deserve disapproval.

Louis Lasagna, M.D.

Reprinted from MEDICAL TRIBUNE, Nov. 19, at request of Dr. A. M. Sackler

treating people with antibiotics after the first 3 to 5 days of home remedy have failed and seek our advice and prescriptions. After all, the bread winner has to be kept on the job, most children have to be kept in school and of course the housewife must be able to care for all of them.

When we read and go to seminars where the great professors tell us to avoid the use of antibiotics because coccidia only viral infections, I always come home feeling guilty and for the next few days refrain from using antibiotics in the treatment of these "drawn out colds"—only to regret it later on when these same people call with a much more deep-seated infection or even pneumonitis.

So it is good to know that others are also using common sense in the treatment of these so-called "common colds."

CHARLES W. BURROUGHS, M.D.  
Trenton, N.J.

Many thanks for publishing Dr. Lasagna's letter.

As one of the many physicians in the area of primary care, I have often felt "defensive" after reading some article implying that I am abusing antibiotics every time I prescribe them. The next time I prescribe one, I'll bear down a little harder on the pen.

I am in a group practice, and I have CBC and culture availability in the office. This helps a lot, but when it comes to the daily decisions of when to use an antibiotic, all of the factors (cost, safety, chance of super-infection, indication of bacterial complication, duration of treatment, etc.) come into play every time we see the "common cold."

JOHN A. MAPPE, M.D.  
Virginia Beach, Va.

I am in the general practice of internal medicine and see many patients weekly similar to the situation de-

scribed by Dr. Lasagna, and I am in complete agreement with him.

KERITH L. WRAAGE, M.D.  
Rockford, Ill.

Dr. Lasagna is quite right when he says that most patients who arrive at our offices have already tried various nostrums for curing their colds. These people are, many times, complicated by a sinusitis and bronchitis or laryngitis. I rarely ever use antibiotics unless there is a definite evidence of bronchitis or any of the above.

At least this is my experience in my practice in a rural section of Virginia.

H. W. FELTON, M.D.  
Deltaville, Va.

Dr. Sackler's interesting article on "the common and not an common cold" stated, "What's good enough for the President of the United States is good enough for our patients, the citizens of the United States."

The entire article revolves around a much more critical issue than whether or not the President has a cold, but rather revolves around the issue as to whether or not those so-called armchair generals who have never seen or treated a patient making decisions regarding possible life-saving treatments that the practicing physicians have to deal with every day.

It is almost akin to armchair policemen making decisions six months later and still not coming to a successful conclusion as to what policemen have to make in split seconds, and criticizing them for the split-second decision that they had to make. Physicians likewise have to make decisions that are meant to be possible life-saving and yet must be able to withstand the criticisms from those who have never had to make a single decision in this respect.

It was a fine, thought-provoking article.

MAYNARD J. AMELON, D.O.  
Detroit, Mich.

## Atherosclerotic Plaque Lowered By Cholestyramine

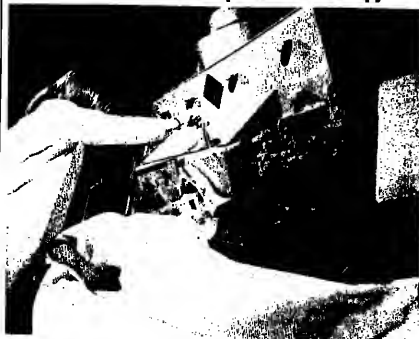
Continued from page 1

Morphologic measurements of atherosclerotic lesions in drug-and-diet treated rhesus monkeys showed that progression of disease had not only stopped, but that there had occurred a "substantial decrease" in the luminal narrowing of the coronaries and "very marked reductions" in the lesion mass of aortic plaques, following a year's treatment, Dr. Wissler reported. Studies by means of labelled cholesterol also demonstrated "a rather remarkable decrease" in both free cholesterol and cholesterol esters in the [aortic] lesions," he said.

In reporting the studies, part of an ongoing investigation on the potential for regression in atherosclerosis, Dr. Wissler stressed that the current findings were made in plaques produced in a relatively short time by an extreme atherogenic diet. Uncomplicated research now underway, he reported, is seeking to determine the possibilities of regression in the non-lipid, collagenous portions of plaques typical of long-term atherosclerosis.

The experimental animals in the cholestyramine study were 24 rhesus monkeys, about five years old, who were fed a high-cholesterol, high-fat diet to induce severe atherosclerotic plaques within 12 months. The diet consisted of ordinary monkey chow enriched with 2% cholesterol and 25% fat. At the outset of the study, all of the monkeys were comparable in serum cholesterol concentration, with levels in general less than 200 mg %. These rose to a peak of 800-1000 at nine months and were at approximately 750 mg % at the end of one year when five of the monkeys were killed and autopsied to serve as a reference group.

## Collaborative Effort Improves Radiotherapy



Cancer patient receives radiotherapy via betatron, administered by a member of the new Cancer COM-RAD Network in New York. A collaboration of nine major metropolitan medical centers, the network uses computers to improve the quality, the design, and delivery of radiotherapy to cancer patients. COM-RAD is based at Mt. Sinai Hospital.

The remaining animals were divided into four groups and followed for an additional year. Group II was maintained on the atherogenic diet, Group III was fed a low-fat, cholesterol-free diet, Group IV received the same diet combined with cholestyramine, and Group V was continued on the atherogenic diet but also received cholestyramine.

### 'Remarkable Drop'

Among the highlights of the findings, Dr. Wissler declared, were these: Cholestyramine added to the atherogenic diet produced a "remarkable drop" in serum cholesterol to about 250 mg %.

• The drug did not lead to a significantly lower serum cholesterol when added to the low-fat low-cholesterol

ration, but it "did sustain what appears to be substantially more regression."

When all of the monkeys were killed at the end of two years, morphologic studies showed "a virtual absence of gross aortic lesions" in some of the animals treated with the combined drug-and-diet regimen, compared with the reference group.

Fat-staining of the plaques showed "even the most severe of the aortic lesions of the three treated groups contained very little lipid (intracellular or extracellular) and showed no evidence of a necrotic center, features that were prominent in both of the untreated groups of aortas," Dr. Wissler reported.

Contributors were Dr. Dragoslav Vesselinovich, James Borzenstijn and Randolph Hughes.

## Kennedy Favors Division of FDA Into 2 Agencies

Continued from page 13

Board, with two full-time chemists and a full-time staff, the outside members to be exempt from civil service salary limits.

The Massachusetts lawmaker said that because of the profound changes called for by his proposals, he would postpone hearings on the legislation until next spring but would meanwhile ask for assessments of the proposals and recommendations from the American Society for Clinical Pharmacology and Therapeutics, the National Academy of Sciences, the Pharmaceutical Manufacturers Association and others.

Dr. Schmidt proposed three procedural changes, some calling for enabling legislation, to help speed drug approval. The first calls for FDA-industry agreement on a study design before any drug trials are undertaken. In past practice, Dr. Schmidt noted, "FDA generally took the position that we would review material when it was submitted and then give our opinion." This approach was not mere nastiness, although it was a bit unfair. It was based on the view that drug development was 'their' business, drug review was 'our' business, and we would lose our objectivity if we participated in a study design."

### 'Staged Approval'

The FDA chief's second recommendation urged "staged approval" or "continued and sequential review" of trial data submitted by a drug company, so that "at any given time, all interested parties know how the tally sheet reads—what their score is and whether they are winning the game."

A major bonus of sequential review, Dr. Schmidt said, is that once a company knows its ongoing studies are approved, it would be able "to invest the large sums required for the remaining clinical research (related to safety, dosage, etc.) without worrying overly that the FDA, in a late stage of the game, will point out a fatal defect."

Dr. Schmidt's third recommendation, not dissimilar to Senator Kennedy's, calls for a more flexible approval system, coupled with a systemic feedback procedure about physician experience with a drug after marketing.

"The greatest single weakness of our present regulatory system is the abysmal reporting by almost all professionals about their drug experiences—good, bad or indifferent," Dr. Schmidt declared. He urged that the FDA be given authority to resume studies of a drug after it has been marketed, and to approve drugs for restricted use, for example, "only in a hospital, only by certain specialists, or only by physicians who had taken a specific training or would agree to report results in a particular manner."

"In effect," he concluded, "these changes might permit earlier appearance in the United States of many drugs, in return for a longer investigation phase controlled by FDA. This seems to me a reasonable tradeoff."

## Vein Grafts Aid Pre-Infarction Angina Patients

Medical Tribune Report

ANAHEIM, CALIF.—"A relatively high percentage" of patients treated by emergency vein-grafting for pre-infarction angina resistant to medical therapy "can look forward to improved prognosis and a normal existence," according to Dr. Cary J. Lambert of the Baylor University Medical Center.

Sixty-one of 95 patients treated by means of aortocoronary bypass were symptom-free, fully productive and not taking medication for angina two-and-a-half to five-and-a-half years postoperatively, Dr. Lambert told the 41st Annual Scientific Assembly of the American College of Chest Physicians.

In addition, 18 other patients consider themselves subjectively better off, at 30- to 67-month follow-up, are under control with anti-anginal medication, Dr. Lambert said. Six in-hospital deaths were ascribed to peri-operative myocardial infarctions. Two deaths were attributed to left main lesions and another to a trapped septal perforator.

Three patients died prior to surgery. Of seven survivors with peri-operative infarctions, five are alive and symptom-free, two have medically manageable angina and none have congestive heart failure, Dr. Lambert asserted. Seven "late deaths" were caused by myocardial infarction, hepatitis, pulmonary embolus, cerebrovascular accident and suicide.

Pointing out that several investigators have attested to the high early mortality and guarded long-term prognosis in patients who develop pre-infarction angina, Dr. Lambert said: "The overall survival of our surgically-treated group at an average follow-up period of 32 months is 86%. It is to be noted that three of our operative deaths

occurred as a result of operating upon a recently infarcted ventricle.

"We feel that greater diagnosticumen and new methods of diagnosis such as the myocardial scan may differentiate evolving infarctions from impending infarctions and thus avert expanding acute infarctions in the increased risk of early surgical intervention."

"All in all, we conclude that direct surgical intervention has a place in the management of patients with pre-infarction angina, particularly when these patients continue to have in-hospital angina."

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indications: For the relief of cerebral and peripheral ischemia associated with arterial spasm.

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**Precautions:** Use with caution in patients with glaucoma. Hepatic hypersensitivity has been reported with gastrointestinal symptoms, jaundice, eosinophilia and altered liver function tests. Discontinue drug if these occur.

**The safety of ethaverine hydrochloride during pregnancy or lactation has not been established; therefore it should not be used in pregnant women or in women of childbearing age unless, in the judgment of the physician, its use is deemed essential to the welfare of the patient.**

**Adverse Reactions:** Although occurring rarely, the reported side effects of ethaverine include nausea, abdominal distress, hypotension, anorexia, constipation or diarrhea, skin rash, malaise, drowsiness, vertigo, sweating, and headache.

**Dosage and Administration:** One capsule three times a day.

**How Supplied:** 100 mg capsules in bottles of 50 and 500.

## Steroids May Be Detrimental in the Treatment of Hepatitis

Medical Tribune Report

CHICAGO—Corticosteroids, commonly used in the treatment of severe liver hepatitis, do not contribute to survival and even may be detrimental, a group of California investigators told the American Association for the Study of Liver Diseases.

A prospective double-blind randomized trial of methylprednisolone showed that more patients died on the corti-

costeroid treatment than on placebo, although the difference was not quite statistically significant.

"Fifty percent of the patients assigned to methylprednisolone died during the 16 week study and only 13 percent of those assigned to placebo died," said Dr. Peter B. Gregory, Assistant Professor of Medicine in the gastroenterology division of Stanford School of Medicine.

Major criteria were chosen to select seriously ill patients. No patient was admitted to the trial if symptoms were present for less than three months. Fourteen patients received methylprednisolone and 15 were given placebo. Dose was 48 mg daily divided for four weeks with a taper to 12 mg at the end.

Initial liver biopsies were obtained in 14 patients before entering the study and as soon as possible after beginning treatment to the remaining 15. All biopsies were coded and interpreted by three observers without knowing the clinical history.

Bridging necrosis was seen in 13 of the placebo group and in 11 of the corticosteroid group. Histologic findings were comparable in the two treatment groups. Two of the placebo group died and seven of the corticosteroid group. Serious side effects of steroid were a contributory cause of death in one patient.

"Follow-up biopsies in those who survived and completed the 16-week study demonstrated chronic active hepatitis in five of eight patients on placebo and one of three patients on methylprednisolone," said Dr. Gregory.

He recommended that the use of corticosteroid for severe liver hepatitis be discontinued until further studies confirm or refute the results.

## Severity of Cervical Cancer Underestimated?

Medical Tribune Report

PHILADELPHIA—Sizeable numbers of cervical cancer patients are now being classified as having microinvasive disease when their condition has actually reached a more serious stage that requires radical hysterectomy.

This is the conclusion of investigators at two medical centers, who recommended adoption of a new definition of microinvasive disease here at the American Cancer Society's National Conference on Gynecologic Cancer.

Drs. Harvey E. Averette, of the University of Miami School of Medicine, and James H. Nelson, of the Downstate Medical Center, Brooklyn, pointed out that the current definition of Stage IA disease includes penetration of cancer cells to a maximum depth of 5 mm beneath the basement membrane.

Instead, they propose that all patients with infiltration of cancer cells into the stroma to a depth of more than 1 mm should be considered as having invasive Stage IB disease. Only disease with less than 1 mm penetration, not accompanied by vascular or lymphatic involvement, should be considered microinvasive and be treated by simple

removal of the uterus alone, they said. Their new definition is described in the American Cancer Society publication "Dysplasia and Early Cervical Cancer," which they cosponsored with Dr. Ralph M. Richart, of the Columbia University College of Physicians and Surgeons.

Dr. Averette commented that medical literature does not provide enough data to define microinvasive disease adequately, but in his opinion 5 mm of invasion is "definitely too much—that's halfway through the cervix."

### Problems with Pathologists

Problems also arise, he added, because pathologists frequently do not measure precisely the depth of penetration into the stroma.

In surveying published accounts of cases of carcinoma of the cervix, Dr. Averette found information on 198 patients treated by radical hysterectomy with pelvic lymphadenectomy. A majority of the reporting investigators specified that depth of invasion had been limited to 5 mm, yet eight of the patients (4 percent of the total) were observed at surgery to have metastasis to

lymph nodes.

Dr. Averette compared these findings with data collected over the past decade at the Miami and Brooklyn medical centers on 162 patients with Stage IA cancer of the cervix, defined as penetration of less than 1 mm without vascular or lymphatic invasion. None of these patients has shown nodal metastasis or recurrence of disease, he emphasized.

To be safe, therefore, the Florida investigator would limit the Stage IA category to patients with a maximum penetration of 1 mm. He believes that anyone else should have radical surgery including removal of the pelvic lymph nodes, supportive tissues of the uterus, and the upper vagina. Ovaries surgery carries a mortality risk of 1%.

Acknowledging that the stand he advocates might seem overly conservative, the investigator agreed that choice of treatment of patients with cancerous penetration between 1 and 3 mm into the basement membrane is still controversial. It has not yet been conclusively determined, he said, whether these patients require radical measures.

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**ELUX**—each ounce represents: Iron and Ascorbic Acid, 16 gm.; Vitamin C, 1.6 gm.; Thiamine Hydrochloride, 10 mg.; Riboflavin, 4 mg.; Nicotinamide, 20 mg.; Cyanocobalamin (Vitamin B12), 100 mcg.; Alcohol 9% by volume.

**Tablets**—each tablet contains: Ferrous Gluconate, 50 mg.; Vitamin C, 50 mg.; Cyanocobalamin (Vitamin B12), 100 mcg.; Liver Fraction 2, 2 mg.; Thiamine Hydrochloride, 2 mg.; Riboflavin, 2 mg.; Nicotinamide, 20 mg.



## Clinical Trials



By Olden

## Pain in the Athlete's Heel

By Dr. PETER SPERRY  
Hon. Secretary, British Association of Sports and Medicine  
Special Tribune Report

MANY of the sportsmen's most disabling medical problems are of simple causation and respond to simple remedies, once the cause is understood. Pain around the heel is frequent in all sports and a moment's pause to consider both footwear and sporting environment will help to put the clinician on the right diagnostic track.

The commonest of the heel disorders are surely blisters due to ill-fitting shoes or failure to wear socks. The simplest—though often overlooked—treatment of blisters is simply to de-roof them, to put on a spritz [alcohol] or Friar's Balsam [compound benzoin tincture] and then raw Elastoplast [adhesive elastic bandage] reshaped to fit the heel.

In this way the irritant effect of a sliding lint dressing is averted and the sportsman can resume his activity forthwith. When shoes are sufficiently ill-fitting, or the underlying calcaneum is sufficiently prominent, persistent friction may lead to the formation of superficial or deep calcaneal burrs which lie respectively superficial and deep to the Achilles tendon insertion at the back of the calcaneum.

## Apparent on Saturday

The diagnostic problem is that in many sportsmen the diagnosis may be fairly apparent on Saturday evening, with a reddened fluctuant swelling in the affected area, but may by Monday or Tuesday show little abnormality. Bursae usually respond to a spell of rest, especially if protective padding of ring type can be devised to avoid further direct pressure on the lesion.

Cuticle often barefoot running is an excellent temporary measure. Thereafter hydrocortisone injection after aspiration may help some to settle down and a small minority give persistent symptoms leading to surgical cure.

Calcaneal bruising is quite common in certain events, most especially in long jumpers and triple jumpers in athletics where a fairly hard take-off board is vigorously struck. Similar lesions are seen in any sportsman who trots or performs on a very hard surface, especially in poorly padded shoes.

The diagnosis is made on the history and confirmed by the finding of tenderness on the postero-inferior aspect of the calcaneum.

Physiotherapy methods such as

short-wave and ultrasonic may be of help here if available but like any periosal bruising, considerable time may be required for the lesion to settle satisfactorily.

## Heel Cups Help

Adequate padding with Sorbo, Plastazote or pre-formed plastic heel cups are available to fit inside sports shoes and these can alleviate symptoms by spreading the stresses on the heel more evenly.

Hydrocortisone injections are usually unwarranted in these situations. It should be remembered that the fat pad under the calcaneum may be quite displaced when the fibrous dividing strands become weakened or disrupted by repeated mechanical insult, so that the athlete loses the natural protection of his own heel pad.

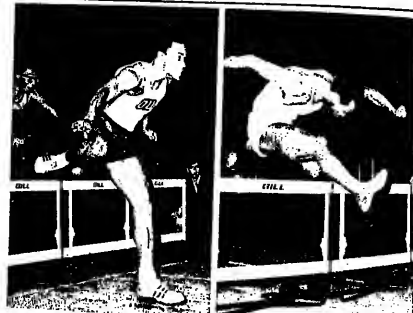
Nothing can restore this anatomically, so padding is a useful prophylactic measure.

The outside possibility of a stress fracture of the calcaneum should not be forgotten in cases of severe or chronic exposure to injury and an X-ray may occasionally be required. Calcaneal fractures are usually dramatic events, following directly upon violent injury, usually a direct fall from a height on to the heels, as may be seen in parachute jumpers.

Calcaneal spurs are often found on X-rays and, in the best medical traditions, blamed for any symptoms that happen to be localized to the lower side of the calcaneum.

As calcaneal spurs are such a common finding, it has always been difficult to assess their role in relation to symptoms. It is likely that the majority of spurs are harmless and best left alone. Certainly standard treatment of most of the lesions around the heel leaves the bony spur intact while relieving the symptoms.

Further forward on the anterior in-



Calcaneal bruising is quite common among hurdle jumpers and other athletes who perform or train on very hard surfaces while wearing poorly padded shoes.

ferior limit of the calcaneum and in the soft tissues immediately adjacent to it is the tensor area found in plantar fasciitis.

This is commonly brought about by running on a hard surface in sensibly padded shoes and probably reflects repeated stress of the longitudinal arch during the three phases of running.

It can be differentiated from spring ligament strain quite simply because in plantar fasciitis there is well localized tenderness very near to the heel, whereas in spring ligament strain the pain is further down the foot and more directly related to the middle of the

unimpaired arch.

Simple plantar fasciitis will respond rapidly to rest and heel padding, but if this fails within two weeks then there is no point in delaying hydrocortisone injection which is gratifyingly effective in the vast majority of cases.

Physiotherapy methods very rarely improve on the time-scale. Spring ligament strain may be treated by foot exercises, sometimes requiring fardie footbaths for preliminary education of the athlete in correct use of his intrinsic foot muscles and by attention to some in-step support if the shoes are obviously inadequately constructed.

## Applications Are Being Accepted for Johananoff International Fellowship

Medical Tribune World Service

MILAN, ITALY—Applications for the Johananoff International Fellowship for Advanced Biomedical Studies for 1976-1977 are presently being accepted by the Mario Negri Institute for Pharmacological Research in Milan.

The award is presented each year to a distinguished scientist for outstanding contributions in one of the following fields: cancer, chemotherapy and immunology; cardiovascular pharmacology; neuropsychopharmacology; or drug metabolism.

Last year's winner was Dr. Herbert S. Schwartz, cancer research scientist at Roswell Park Memorial Institute in Buffalo, N.Y. He received the fellowship on the basis of his original research on the factors involved in cytotoxic actions of anticancer drugs.

Under the terms of the award, Dr. Schwartz is spending one year at the Institute in Milan investigating the factors and mechanisms determining the selective cytotoxicity of DNA altering agents which interact directly with DNA.

DNA-reactive drugs, recently introduced into cancer treatment, include adriamycin and daunorubicin. Both are anthracycline antibiotics.

Dr. Schwartz' main objective is to prepare a comprehensive review which will assemble and evaluate already existing knowledge in his field.

Applications for the 1976-1977 award should be submitted no later than January 28, 1976 to "The Johananoff Fellowship Committee, Istituto di Ricerche Farmacologiche 'Mario Negri', Via Erzilia, 62, 20157 Milan, Italy."



## Soul Disco Hypertension

For reasons that we still can't understand, we were drawn into a Lexington Avenue music store where we stood gawking. Then we saw something that made us decide that that was why we came. It was a 45 rpm record called *Hypertension*, distributed by Buddha Records, written and conducted by Paul L. Kyser. We bought it.

"Do you know what you're doing?" asked the saleslady. "That record just came in five minutes ago and you walk in and buy it. Two sides, both *Hypertension*. Do you know what you're getting?"

"No, but you have to be with it, man. Hypertension's my thing," we responded, which is the only way out of a situation like that. Just be cool.

## On Part I...

We took it home and played it. On Part I there were lyrics: Part II stuck to the instrumental. The beat was steady throughout—much like a heart-beat, we told ourselves. On the instrumental side, things steadily got more cacophonous, pressurized, wildly electronic and even, we'd say, twangy in an Oriental rock way. We took it up with our musician-in-residence. "Soul disco," he said. "You bought that?" He fainted dead away.

But our greatest problem lay in the lyrics. We couldn't understand them past the time and when we did, we couldn't connect them with hypertension, renal, aphygmanometers, salt or anything else we normally look for.

## Talking to Paul Kyser

Instead, we got on the phone and finally, with the help of Michael Milrod of Buddha Records, we were talking to Paul L. Kyser, the composer and leader of the Calendar group that recorded the music. He turned out to be a 27-year-old musician who had studied at Rutgers and with the late Hal Welles, an arranger for the Ed Sullivan show. In eight years, Kyser has had two records in the "million-seller" class and 15 hits. One was *Body and Soul*, *That's the Way It's Got to Be*, which is not to be confused with the original song; the other was *Ain't It Good Enough?* Among his other hits were *My Ebony Princess* and *Where Were You When I Needed You?*

So we explained we needed him because we didn't "get" the lyrics on *Hypertension*. He laughed and said, "Look, there's two kinds of hypertension. There's the kind my mother has. That's medical hypertension—I forget what her blood pressure is but it's really sky-high. But that's medical hypertension and if you get all worked up and upset you can get that kind."

"And then there's another kind of hypertension—and that's when people, like all my friends, have tension and pressure. Everything's frantic, uptight, it's the scheduler, the timetable, the deadline, the landlord, the traffic, everything pouring in on you. A lot more people have this hypertension, this

pressure due to the way they're working and living. You get excited. It gives you headaches. You're all wound up. It affects the rich and the poor. It's all around me—and that's why I love writing songs. They're about me and my people, everyone I know. I love writing a message in my songs."

He ran hastily through the lyrics for us, clarifying what the singers' phrasing sometimes blurred, and promised to send us a lyric sheet. We thought we understood things a little better.

It would make a lot of sense, we mused, since the incidence of hypertension among black people is so high, for the National Heart and Lung Institute to underwrite some real hypertension blues and rock just to reach all those young people who never turn up for screening or treatment. Dear Ted Cooper, we began...

## Clearing Things Up

But to get back to the lyrics, when we got Paul Kyser's lyric sheet, we at last understood a great deal. The song is titled *Hypertension—not Hypertension*. This is why Paul Kyser was talking about two kinds of hypertension. What he said was now perfectly clear. And this is why his lyrics, so inexplicable to us at first, go:

Well, well, well, well,  
let me be, I gotta be me,  
who puts me through this misery

I work all day 'n drink all night  
trying to make the situation right  
my destiny's on a shaky course,  
just as shaky as the job  
I just lost

My baby brother is in jail,

'n I'm out here trying  
to hustle up his bail,  
My landlord is bugging the (beep) 'n  
outta me  
and I feel like I'm gettin'  
HYPERTENSION, don't you  
mention

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